

Message Text

UNCLASSIFIED

PAGE 01 STATE 018784

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ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-05 RSC-01 /045 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

ARA/EP - MR CLARKE INFO

EA/ANP - MR LANGE INFO

EUR/NE - MR FLOYD INFO

EA/PRCM - MR HOLMES INFO

----- 057218

R 271951Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY QUITO

AMEMBASSY WELLINGTON

AMCONSUL HAMILTON

AMCONSUL HONG KONG

UNCLAS STATE 018784

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, BD, EC, HK, NZ

SUBJECT: DRUG RECALL - SUB-POTENCY

1. FDA ADVISES THAT AN TX (PRESCRIPTION) DRUG FOR INTRAVENOUS INJECTION IN SINGLE DOSE VIALS AND VIAL CARTONS (12 VIALS TO A CARTON) LABELED IN PART NDC -006-333-50 INTRAVENOUS SODIUM EDECRIN (SODIUM ETHACRYNATE, MSD) 50 MG. ETHACRYNIC ACID EQUIVALENT CAUTION: XXX FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS XXX MERCK SHARP & DOHME, DIVISION OF MERCK & CO., INC., SUMNEYTOWN PIKE, WEST POINT, PA. 19435, ARE BEING RECALLED TO THE USER LEVEL BECAUSE THE PRODUCT IS SUB-POTENT. A TOTAL OF 56 LOTS ARE INVOLVED - ALL LOTS BEAR A LOT NUMBER WITH THE SUFFIX "S". THE LOTS FALL BELOW THE USP LIMITS OF 92 - 110 PERCENT OF DECLARED POTENCY. THE AVERAGE POTENCY OF ALL LOTS IS 82.6 PERCENT WITH A RANGE OF FROM 73 TO 95.8 PERCENT.

2. FOREIGN CONSIGNEES, AS FOLLOWS:

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A. MERCK, SHARP & DOHME (INTERNATIONAL) LTD., BERMUDIANA
ROAD, JAMILTON, BERMUDA.

B. MERCK, SHARP & DOHME (I.A.) CORP., AVENIDA DE LAS AMERICAS
EDIFICIO SONAPAL, GUAYAQUIL, ECUADOR.

C. MERCK, SHARP & DOHME (ASIA) LTD., AMERICAN INTER-
NATIONAL ASSURANCE BLDG., 8TH FLOOR, 1 STUBBS ROAD, HONG
KONG, B.C.C.

D. MERCK, SHARP & DOHME (NEW ZEALAND) LTD., PLUNKET AVENUE,
WIRI, AUCKLAND, NEW ZEALAND

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY ARE FAMILIAR WITH THE FACTS OF THE RECALL.
KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, STOCKPILE DISPOSAL
Control Number: n/a
Copy: SINGLE
Draft Date: 27 JAN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE018784
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750030-0626
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750117/aaaaaoso.tel
Line Count: 77
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: greeneet
Review Comment: n/a
Review Content Flags:
Review Date: 03 DEC 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <03 DEC 2003 by MaustMC>; APPROVED <30 DEC 2003 by greeneet>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: DRUG RECALL - SUB-POTENCY
TAGS: ETRD, EIND, TBIO, BD, EC, HK, NZ, MERCK SHARP & DOHME
To: QUITO MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006